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Subject: Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Discogenic low back pain is a common, multifactorial pain syndrome that involves low back pain without radicular symptoms findings, in conjunction with radiologically confirmed degenerative disc disease.

Electrothermal intradiscal annuloplasty therapies use radiofrequency energy sources to treat discogenic low back pain arising from annular tears. These annuloplasty techniques are purported to decrease pain arising from the annulus by thermocoagulating nerves in the disc and tightening annular tissue.

Vertebral body endplates have been proposed as a source of lower back pain, caused by intraosseous nerves. The basivertebral nerve enters the posterior vertebral body and sends branches to the superior and inferior endplates. Vertebrogenic pain, transmitted via the basivertebral nerve, has been purported to occur with endplate damage or degeneration.

The Intracept® Intraosseous Nerve Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least 6 months duration, that has not responded to at least 6 months of conservative care.

Summary and Analysis of Evidence: Two RCTs on intradiscal electrothermal annuloplasty have reported conflicting results, with one RCT (Pauza et al, 2004) finding a benefit for intradiscal electrothermal annuloplasty, and the other RCT (Freeman et al, 2005) finding no benefit. The most recent RCT identified was from 2005. No recent literature on intradiscal electrothermal annuloplasty has been identified.

For percutaneous intradiscal radiofrequency thermocoagulation, two sham-controlled randomized trials showed no evidence of a benefit. One found trial that only 1 of 14 patients was considered a treatment

success (Barendse et al, 2001). The other was terminated after a blinded interim analysis showed no trend to benefit compared with sham (Kvarstein et al, 2009).

Two industry-sponsored RCTs have assessed use of biacuplasty to treat chronic low back pain. In one, only 6% of subjects screened met the strict inclusion and exclusion criteria for the study (Kapural et al, 2013). Significant differences in outcomes were observed at 6 months, but not at 1 month or 3 months, and the definition of successful treatment appears to have been post hoc. Kapural et al (2015) reported on the unblinded 12-month follow-up from this trial in 2015. Improvements continued through 12 months. However, the change in Oswestry Disability Index score was modest. Opioid usage did not decrease significantly. In the second multicenter RCT (Desai et al, 2016), 63 patients met inclusion criteria, which included a positive result on provocation discography. There was a significant treatment effect for the primary outcome measure, but not the secondary outcome measures. This trial was not sham-controlled, and it was not reported whether it was adequately powered. Additional sham-controlled trials in a broader population of patients are needed to determine the effect of this treatment with greater certainty.

Fischgrund et al (2018) conducted a randomized, double-blind, sham controlled study (SMART trial) of basivertebral nerve ablation using the Intracept system in 225 participants from the U.S. and Europe. Patients had chronic isolated lumbar pain that had not responded to at least 6 months of nonoperative management. Additional study inclusion criteria were a minimum Oswestry Disability Index of 30 points (on a 100 point scale), a minimum visual analog scale of 4, and Modic type 1 or 2 changes at the vertebral endplates of the levels targeted for treatment. Treatment was limited to a minimum of 2 and a maximum of 3 consecutive vertebral levels from L3 to S1. The active treatment group (n=147) received radiofrequency and the sham group (n=78) underwent the same protocol for the same overall duration as the treatment group; however, the radiofrequency treatment was simulated. Patients were blinded to the group assignment for 1 year, at which time those in the sham arm were allowed to cross over [57 (73%) elected to do so] and receive the Intracept treatment. The primary endpoint of the original study was comparative change in Oswestry Disability Index from baseline to 3 months, and in the intent-to-treat analysis there was no statistically significant difference in this outcome between groups at this time point. There was a difference between groups in the 3-month per protocol analysis (mean Oswestry Disability Index improved 20.5 and 15.2 points in the treatment and sham arms, respectively; p=.019). However, at the 12 month per protocol analysis, the difference in mean Oswestry Disability Index between groups was no longer statistically significant. Pain severity, measured by visual analog scale, was not significantly different between groups at 3 months (p=.083) but there was significantly greater improvement in the treatment group at 6 and 12 months. The 24 month follow-up results were reported for the active treatment group from the SMART trial (Fischgrund et al, 2019). Of the per protocol population treated with ablation (treatment arm), 106 (83%) completed a 24-month follow-up visit. A durable Oswestry Disability Index mean improvement was observed (23.4 points). Data for Oswestry Disability Index outcomes were not available for the sham group because of the high crossover rate. Therefore, long-term comparative outcomes are not available. Five year results were reported for the 100 U.S. patients from the treatment arm from the original SMART trial who were available for follow-up (Fischgrund et al, 2020). Mean Oswestry Disability Index scores improved from 42.8 to 16.9 at 5 years, a reduction of 25.9 points. Mean reduction in visual analog scale score was 4.4 points (baseline 6.7, p<.001).

The INTRACEPT trial was an open-label RCT conducted at 20 U.S. sites (Khalil et al, 2019). A total of 140 patients with lower back pain of at least 6 months duration, with Modic Type 1 or 2 vertebral endplate changes between L3 and S1, were randomized to undergo radiofrequency ablation of the basivertebral nerve or continue standard care. Standard care consisted of pain medications, physical therapy, exercise, chiropractic treatment, acupuncture, and spinal injections; the specific treatment(s) administered were determined by the treating investigator in conjunction with the patient. Treatment of up to 4 vertebrae in non-consecutive levels from L3 to S1 was allowed. The primary study endpoint was change in Oswestry Disability Index at 3 months. A pre-planned interim analysis was undertaken when 60% of participants reached the 3 month follow-up (n=51 in the treatment group and n=53 in the standard care group), and reported statistically significant differences between groups on all patient-reported outcome measures, favoring the treatment group. The study was halted and the individuals were allowed to cross over to the treatment arm. Study limitations include short term follow-up, lack of a sham group, and allowance of crossover at 3 months. Twelve month follow-up results were reported from the INTRACEPT trial; after a median of 175 days post-randomization, 92% of patients initially randomized to the standard care arm elected to receive early treatment with basivertebral nerve ablation (Smuck et al, 2021). Six month results for the Oswestry Disability Index were significantly improved with basivertebral nerve ablation (n=66) compared to standard care (n=74) (least squares mean difference between groups, -24.5; 95% CI, -29.4 to -19.6; p=.0001). Improvements in the Oswestry Disability index and mean visual analog scale that were reported among patients initially treated with basivertebral nerve ablation were maintained throughout the 12-month study period, with reported reductions of -25.7±18.5 points, and -3.8±2.6 cm, respectively (p<.001 for both comparisons to baseline). Improvements in pain, function, and quality of life were reported at 24 months; however, these results were also not comparative (Koreckij et al, 2021). The lack of comparative data beyond 6 months due to the high rate of crossover is a limitation of this trial.

Mekhail et al (2023) conducted a systematic review and meta-analysis to determine the relative effectiveness and safety profiles of percutaneous and minimally invasive interventions for chronic low back pain. Twenty-seven studies were included. BVN ablation was found to provide statistically significant improvements in VAS and ODI scores for 6-, 12- and 24-month follow-up ($P \leq 0.05$). Biological therapy and multifidus muscle stimulation were the only 2 treatments with both VAS and ODI outcomes not significantly different from BVN ablation at 6-, 12-, and 24-month follow-up. All outcomes found to be statistically significant represented inferior results to those of BVN ablation. Insufficient data precluded meaningful comparisons of SF-36 and EQ-5D scores. The serious adverse event (SAE) rates for all therapies and all reported time points were not significantly different from BVN ablation except for biological therapy and multifidus muscle stimulation at the 6-month follow-up. The authors concluded that “BVN ablation, biological therapy, and multifidus stimulation all provide significant, durable improvements in both pain and disability compared with other interventions, which provided only short-term pain relief. Studies on BVN ablation reported no SAEs, a significantly better result than for studies of biological therapy and multifidus stimulation”. The authors stated that limitations of this review included the ability of this study to estimate accurate effects for each tested treatment, and to determine significant differences between BVN and other treatments, was dependent on the state of the published literature on these topics. This systematic review/meta-analysis reached a conclusion regarding the effectiveness of the Intracept procedure by providing weight to lower quality studies; however, the only sham-controlled study of the Intracept procedure failed to achieve its primary endpoint.

A systematic review (Nwosu et al, 2023) examined the effectiveness of intraosseous basivertebral nerve RFA in treating non-radiating axial chronic LBP compared to standard therapy, sham, or without contrast. There were 286 articles in total; however, only 11 publications with extensive data on 413 participants matched the inclusion criteria and were used for this review. The authors stated that "a good number of patients in the basivertebral nerve ablation (BVNA) arm reported complete pain resolution demonstrating therapy success and the superiority of BVNA over sham and standard treatment". However, they further stated that "the findings of the existing investigations require confirmation by non-industry-funded, large-scale, high-quality trials using generalizable study participants".

Schnapp et al (2023) published the clinical outcomes for 16 consecutively treated patients with basivertebral nerve ablations utilizing in the INTRACEPT® device in a community practice setting. Evaluations were performed at baseline, 1 month, 3 months, and 6 months. The Oswestry Disability Index (ODI), Visual Analog Scale (VAS), and SF-36 were recorded in Medrio electronic data capture software. All patients (n = 16) completed the baseline, 1 month, 3 months, and 6 months follow-up. The authors concluded that "basivertebral nerve ablation appears to be a durable, minimally invasive treatment for the relief of chronic low back pain that can be successfully implemented in a community practice setting". The authors acknowledged several limitations of their study: 1) small study size, following only 16 patients; 2) absence of controls; and 3) other therapeutic procedures were not specifically withheld post-BVNA.

POSITION STATEMENT:

Percutaneous annuloplasty (eg, intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain or other indications is considered **experimental or investigational.**

Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) for the treatment of vertebrogenic back pain is considered **experimental or investigational**.

There is insufficient published clinical evidence to support the safety and effectiveness of these procedures.

BILLING/CODING INFORMATION:

CPT Coding:

22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level (**investigational**)
22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more levels (list separately in addition to code for primary procedure) (**investigational**)
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral **(investigational)**
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure) **(investigational)**

REIMBURSEMENT INFORMATION:

Refer to Section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Thermal Intradiscal Procedures (TIPS) (150.11) located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Electrothermal: an electrosurgical appliance used for cutting.

Intracept procedure: uses a radiofrequency probe to ablate the intraosseous basivertebral nerve in chronic low back pain.

RELATED GUIDELINES:

Automated Percutaneous Discectomy, Laser Discectomy, Percutaneous Endoscopic Discectomy, and DISC Nucleoplasty, 02-61000-32

OTHER:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Other terms associated with thermal intradiscal procedures:

Accutherm

Baylis Pain Management Cooled Probe

discTRODE

Oratec Nucleotomy Catheter

Radionics Disc Catheter System

SpineCath® Intradiscal Catheter,

TransDiscal electrodes

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/25/24.

GUIDELINE UPDATE INFORMATION:

04/17/00	New Medical Coverage Guideline – investigational.
09/15/01	Annual review of investigational status – no changes.
09/15/02	Reviewed – continue investigational.
09/15/03	Reviewed – no change.
07/01/04	3rd quarter HCPCS coding update; consisting of the addition of 0062T and 0063T.
09/15/04	Review and revision to guideline; consisting of updated references, addition of PIRFT to Description section; addition of investigational statement for PIRFT; and MCG name changed from Intradiscal Electrothermal Annuloplasty (IDET) to Intradiscal Electrothermal Annuloplasty (IDET™) and Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT). No change to investigational status.
10/01/04	4th quarter HCPCS coding update; consisting of deletion of HCPCS codes S2370 and S2371.
09/15/05	Review and revision of guideline; consisting of updated references.
09/15/06	Review and revision of guideline; consisting of updated references.
11/15/06	Revision of guideline.

01/01/07	HCPCS coding update consisting of the revision of 0062T and the addition of 22526 and 22527.
07/15/07	Annual review, investigational status maintained, reformatted guideline, references updated.
09/15/08	Review and revision of guideline consisting of updated references.
10/15/09	Scheduled review; added position statement for IDB; changed title of guideline; updated references.
01/01/10	Annual HCPCS coding update: removed 0062T and 0063T; revised descriptor of 22527.
09/15/11	Scheduled review; position statement unchanged; references updated.
01/15/13	Scheduled review; position statement unchanged; references updated.
02/15/14	Annual review; position statement unchanged; Program Exceptions section updated; references updated.
02/15/15	Annual review; formatting changes; position statement unchanged; Program Exceptions section updated; references updated.
11/01/15	Revision: ICD-9 Codes deleted.
02/15/20	Scheduled review. Revised MCG title, description, and index terms. Maintained position statement and updated references.
02/15/22	Scheduled review. Revised description and added coverage statement for intraosseous radiofrequency ablation (Intracept® procedure) (coverage statement moved from MCG 02-61000-34 Neurolysis/Ablation). Revised definitions and CPT coding. Updated references.
12/15/22	Revision. Updated references and maintained position statement.
05/25/23	Update to Program Exceptions section.
10/15/23	Scheduled review. Revised description. Maintained position statement and updated references.
08/15/24	Scheduled review. Revised description. Maintained position statement and updated references.